Claims 1 and 11 have been drafted to clearly point out that the lubricating agent is either:

- in admixture with the other tabletting excipients and on the surface of the tablet, the greater part being on the surface of the tablet; or
- on the surface of the tablet.

Claims 1, 3-6, 8-11 are rejected under 35 USC 102(e) as being anticipated by Liu etal. (US patent n°6,465,009).

Applicants respectfully disagree.

In fact, Liu et al. does not describe nor suggest a tablet in which a lubricating agent is present as a tabletting excipient; said lubricating agent being present on the surface of the tablet or on the surface of the tablet and inside the tablet.

When a lubrication agent is used in Liu et al., it is present inside the tablet only.

Claim 1 is thus novel in view of liu et al.

Since claims 2 to 10 and 13 to 18 depend on claim 1 , they are also novel.
Claim 11 relating to the process for manufacturing the tablet according to claim 1, is also novel.

Since claims 12, 19 and 20 depend on claim 11, they are also novel.

Claims 1-12 are rejected under 35 USC §103(a) as being obvious over Liu et al.

Applicants respectfully disagree.

The invention consists in a tablet in which the lubricant is not, as usual, in admixture with the other tabletting excipients but is
either :

- a part of the lubricant in admixture with the other tabletting excipients and
- the other part on the surface of the tablet, said part being the greater part,

or :

- only on the surface of the tablet.

The fact that the lubricant is not present only in admixture wit the other tabletting excipients but also on the surface of the tablet allows the tablets to disintegrate in less than 40s and to present a strength suitable for obtaining good friability property.

According to Liu et al., the lubricant is added during the wet granulation step with the other excipients, before the compression of the tablet and, it is indicated that the good properties of friability of the tablets result from a post treatment of the tablets consisting in humidification and drying step.

The person of skilled in the art could thus not deduce from Liu et al. the invention which consists in a tablet in which the lubricant is present inside the tablet and on the surface of the tablet.

Claim 1 is thus inventive in view of Liu et al.

Since claims 2 to 10 and 13 to 18 depend on claim 1 , they are also inventive.
Claim 11 relating to the process for manufacturing the tablet according to claim 1, is also inventive.
Since claims 12, 19 and 20 depend on claim 11, they are also inventive.

It is submitted that the application is now in proper form for allowance and favourable consideration is respectfully submitted.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

By: _____

Alan H. Bernstein
Registration No. 19,315
Seven Penn Center, 12th Floor
1635 Market Street
Philadelphia, PA 19103-2212
215/567-2010
Attorney for Applicants
Customer No. 03000

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ATTACHMENT B

Marked-up version of the claims

1.(amended) A rapidly disintegrating tablet similar to those designed to disintegrate in the mouth on contact with saliva in less than 30 seconds, forming an easy-to-swallow suspension, and based on an active substance in the form of coated microcrystals or microgranules, and a mixture of excipients including at least one disintegrating agent, a soluble agent and a lubricating agent, wherein the lubricating agent is in powder form and [at least a major amount] the greater part or the totality of it is distributed on the tablet surface and its friability, measured as specified in the French Pharmacopoeia (10th Edition, V.5.1 - Friability of Tablets, January 1993), is less than 1 %, [and preferably less than 0.5 %,] whereby said tablet can be packaged by standard processes and has the required and adequate hardness to enable it to be removed with ease from the blister pack in which it is packed, by perforating the seal thereof by pushing the tablet, with a substantially reduced risk of the tablet breaking during removal.

2. (amended) Tablet in accordance with Claim 1, wherein its largest dimension is greater than 5 mm [, is preferably greater than 17 mm and may be as much as 25 mm].

3. (amended) Tablet in accordance with Claim 1, wherein the lubricating agent is selected from the pharmaceutically acceptable lubricating agents which have a melting point of at least 35°C[, and preferably higher than 50°C].

4. Tablet in accordance with Claim 1, wherein the lubricating agent is selected from the group including magnesium stearate, sodium stearyl fumarate, stearic acid and micronized polyoxyethylene glycol.

5. Tablet in accordance with Claim 1, wherein the lubricating agent is magnesium stearate.

6. (amended) Tablet in accordance with claim 1, wherein the quantity of lubricating agent is in the range 0.2 to 10 parts per 1000 (weight of lubricating agent / total weight of tablet)[, and is preferably in the range 3 to 6 parts per 1000 (weight of lubricating agent / total weight of tablet)].

7. (amended) Tablet in accordance with one of Claim 1, wherein the lubricating agent has a particle size distribution such that its constituent particles adhere when it is sprayed against a surface[, preferably less than 30 microns and more preferably still, less than 10 microns].

8. (amended) Tablet in accordance with Claim 1, wherein the disintegrating agent is selected from the group including [in particular] cross-linked sodium

carboxymethylcellulose, known in the industry as croscarmellose, crospovidone and their mixtures.

9. Tablet in accordance with Claim 1, wherein the mixture of excipients may include a permeabilising agent, a solubilising agent, sweeteners, flavors and colorings.

10. Tablet in accordance with Claim 1, wherein it is designed to be packaged in blisters composed entirely of aluminum, which may in addition include a cover of a plastic material which is to be torn off before opening.

11. Process for the production of a tablet in accordance with Claim 1, wherein the process involves the following sequence of steps:

- choosing, firstly, an active substance in the form of coated microcrystals or microgranules, and secondly, a set of excipients including a disintegrating agent, a soluble agent, and also a lubricating agent;
- mixing the active substance and the excipients with the exception of [at least] the greater part or the totality of the lubricating agent;
- feeding a quantity of this mixture necessary to form a tablet into the cavity of a compression device within which the mixture is to be compressed and onto the walls of which the necessary quantity of lubricating agent has been applied in advance;
- compressing the mixture and ejecting the tablet formed.

12. (amended) Process in accordance with Claim 11, wherein the compression forces are in the range 3 kN to 50 kN[, preferably in the range 4 kN to 40 kN, or more preferably still, in the range 5 kN to 25 kN].

13. (new) Tablet according to claim 1, wherein its friability is less than 0.5%.

14. (new) Tablet in accordance with Claim 2, wherein its largest dimension is greater than greater than 17 mm.

15. (new) Tablet in accordance with claim 3, wherein the lubricating agent is selected from the pharmaceutically acceptable lubricating agents which have a melting point higher than 50°C.

16. (new) Tablet in accordance to claim 6, wherein the quantity of lubricating agent is in the range 3 to 6 parts per 1000 (weight of lubricating agent / total weight of tablet).

17. (new) Tablet in accordance with claim 7, wherein the lubricating agent has a particle size distribution less than 30 microns.

18. (new) Tablet in accordance with claim 17, wherein the lubricating agent has a particle size distribution less than 10 microns.

19. (new) Process in accordance with Claim 12, wherein the compression forces are in the range 4 kN to 40 kN.

20. (new) Process in accordance with Claim 19, wherein the compression forces are in the range 5 kN to 25 kN.